

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0467]

DDM	
Display Date	6-29-05
Publication Date	6-30-05
Certifier	D. Hawkins

**“Guidance for Industry: Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection”;
Withdrawal of Guidance**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance entitled “Guidance for Industry: Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection” (May 2005 guidance) that was issued on May 6, 2005. A guidance entitled “Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,” dated June 2005, is being announced elsewhere in this issue of the **Federal Register**, and supersedes the May 2003 guidance entitled “Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection” (May 2003 guidance) (68 FR 25897).

DATES: *[Insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

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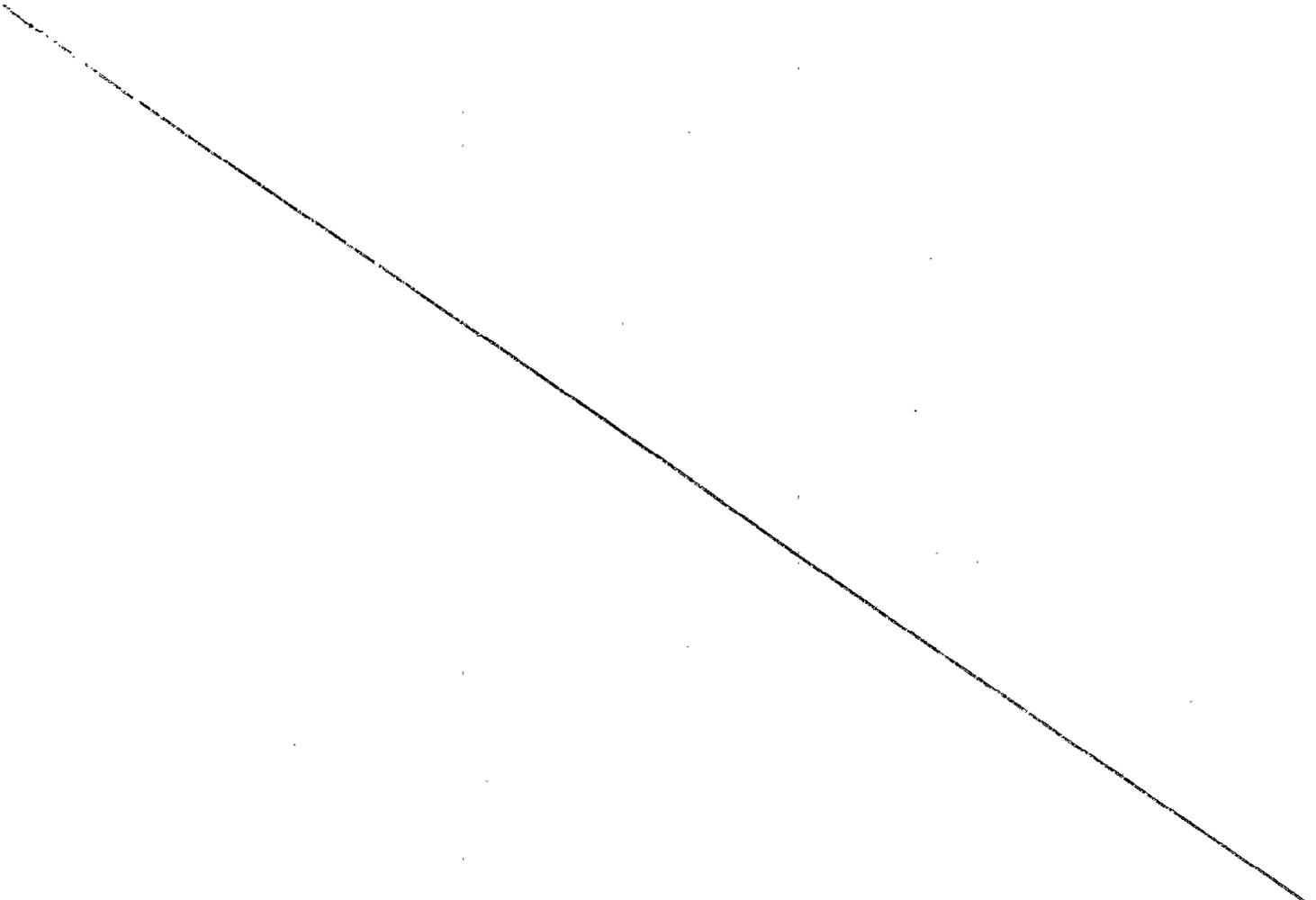
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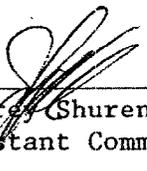
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SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 23, 2005 (70 FR 29529), FDA announced the availability of the May 2005 guidance. This guidance removed FDA's previous recommendation concerning deferral of donors of Whole Blood and blood components for transfusion and for further manufacturing use on the basis of a specific donor question related to West Nile Virus infection (i.e., to defer donors each year between June 1 and November 30 when the donor reports a history of fever with headache in the past week). Donor deferral based on this information was originally recommended in the May 2003 guidance. The guidance entitled "Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection," dated June 2005, announced elsewhere in this issue of the **Federal Register**, supersedes the May



2003 guidance and does not recommend donor deferral based upon a reported history of fever with headache in the week prior to donation. Therefore, the May 2005 guidance is being withdrawn because it is no longer necessary.

Dated: 6/24/05
June 24, 2005



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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